

## REMARKS

Prior to Examination, entry of the claim amendments and consideration of the following remarks is requested. The following remarks address the rejections set forth in the Office Action dated October 18, 2003.

A separate petition for a 1-month extension of time accompanies this amendment.

### I. Amendments

Claims 1-11 and 13-15 are cancelled.

New claims 18-26 are based on the original claims, but are recast as method of treatment claims. Specifically:

- claim 18 finds support in original claim 1 and on page 13, line 3;
- claim 19 is based on original claim 13;
- claim 20 is based on original claim 2;
- claim 21 is based on original claim 3;
- claim 22 is based on original claim 4;
- claim 23 finds support on page 13, lines 8-12.
- claims 24-26 find support in original claim 16.

Accordingly, the claim amendments add no new matter.

### II. Rejection under 35 U.S.C. §102(e)

Claims 1-3, 11, and 13-15 were rejected under 35 U.S.C. §102(e) as being anticipated by Soos *et al.* (U.S. Patent No. 6,372,206). This rejection is respectfully traversed in view of the foregoing claim amendments and following remarks.

#### A. The Invention

Claim 18 is directed to a method for treating hepatitis C virus (HCV) in a subject, by orally administering interferon-tau (IFN $\tau$ ) at a dosage effective to stimulate bloodstream levels of 2', 5'-oligoadenylate synthetase relative to bloodstream levels of 2', 5'-

oligoadenylate synthetase (OAS) prior to treatment. The oral administration continues until improvement of the subject's condition is observed.

B. The Cited Art

Soos *et al.* teach oral administration of IFN- $\tau$  for treatment of autoimmune disorders, cell proliferative disorders, and viral disease. The IFN- $\tau$  is given at dosage concentrations of between  $10^5$  to  $10^8$  units per day.

C. Analysis

According to the MPEP § 2131: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

The pending method claims require oral administration of IFN $\tau$  to a human at a dosage effective to stimulate bloodstream levels of 2', 5'-oligoadenylate synthetase (OAS).

Soos *et al.* fails to expressly disclose this claim element. Specifically, nowhere does Soos *et al.* teach that IFN $\tau$  could be orally administered at a dose effective to stimulate bloodstream levels of 2', 5'-oligoadenylate synthetase (OAS) in a human subject suffering from hepatitis virus C. There is no evidence in Soos *et al.* to suggest that a non-human IFN, as is IFN $\tau$ , would have any effect on human blood OAS levels. Thus, there is no express anticipation by Soos *et al.*

Nor does Soos *et al.* inherently anticipate the present method claims. To show inherency, it is necessary to show that the prior art in question "necessarily produce the newly claimed effects, and that a person skilled in the art would recognize that the newly claimed effects were necessarily achieved." (*Continental Can Co. USA, Inc. v. Monsanto Co*, 948 F. 2d. 1264, 20 USPQ2d 1746 (Fed. Cir. 1991). Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. (*In re Robertson*, 169 F. 3d 743, 49 USPQ2d 1949 (Fed Cir. 1999, quoting from *In re Oelrich*, 666 F.2d 578, 212 USPQ 323 (CCPA, 1981).

Soos *et al.* discloses treatment of various conditions with orally administered IFN $\tau$ , however, there is no evidence in the teaching to suggest that any specifically disclosed IFN $\tau$  dose, or that every IFN $\tau$  dose within a specified range in the prior art, would produce a measurable increase in human blood OAS levels. Unless blood OAS levels are actually measured following IFN $\tau$  dosing, or unless oral IFN $\tau$  doses are predetermined from patients with known conditions, actual OAS blood level response to any given dose of IFN $\tau$ , would be a matter of conjecture, and thus not an inherent property. Accordingly, Soos *et al.* does not inherently anticipate the present claim.

Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §102(e).

### III. Rejection Under 35 U.S.C. § 103

Claims 4-10 were rejected under 35 U.S.C. §103 as allegedly obvious in view of Soos *et al.* (U.S. Patent No. 6,372,206). This rejection is respectfully traversed for the following reason.

Previously pending claims 4-10 were directed to specified dosages of the oral, IFN $\tau$  composition, ranging between  $10^8$ - $10^{10}$  Units. To the extent the rejection is applicable to the amended claim set, it is addressed with respect to new claim 22, which is based on previously pending claims 4-10.

Summaries of the present invention and of the cited Soos *et al.* document are given above.

#### A. Analysis

According to the M.P.E.P. § 2143.03, "to establish a prima facie case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. All words in a claim must be considered in judging the patentability of that claim against the prior art." [citations omitted].

The pending method claims require oral administration of IFN $\tau$  to a human at a dosage effective to stimulate bloodstream levels of 2', 5'-oligoadenylate synthetase (OAS).

Soos *et al.* nowhere mentions that oral administration of IFN $\tau$  would induce OAS in the bloodstream. Since Soos *et al.* is completely silent on the ability of IFN $\tau$  to achieve this stimulation of OAS, it cannot be argued that a person skilled in the art would know how to select an effective IFN $\tau$  dose, in accordance with the claim, because one skilled in the art would not be aware of the target goal (elevated blood OAS).

Accordingly, since the cited art does not teach or suggest all of the features of the present claims, Soos *et al.* cannot be said to render the claimed invention obvious. Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103(a).

**IV. Conclusion**

In view of the above amendments and remarks, the applicants submit that the claims now pending are in condition for allowance. A Notice of Allowance is, therefore, respectfully requested.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4402.

Respectfully submitted,

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